IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

STEVEN SCHABEL and ALLYSON SCHABEL	)	COMPLAINT AND DEMAND FOR JURY TRIAL
Plaintiff,	)	
v.	)	
	)	Case No. 14 C 1748
	)	MDL No. 2545
ABBVIE, INC., ABBOTT LABORATORIES, INC, and AUXILIUM PHARMACEUTICALS, INC. BESINS HEALTHCARE, INC.; BESINS HEALTHCARE, S.A.; UNIMED PHARMACEUTICALS, LLC F/K/A UNIMED PHARMACEUTICALS, INC.;	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Steven and Allyson Schabel (hereinafter individually and collectively referred to as "Plaintiff"), husband and wife, complaining against Defendants, AbbVie Inc., Abbott Laboratories Inc., Besins Healthcare, Inc., Besins Healthcare, S.A., Unimed Pharmaceuticals, LLC f/k/a Unimed Pharmaceuticals, Inc. and Auxilium Pharmaceuticals, Inc. hereinafter individually and collectively referred to as "Defendants") states as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. INTRODUCTION

1. This case involves the prescription drug AndroGel, which is manufactured, sold, distributed and promoted by the Defendants AbbVie Inc., Abbott Laboratories Inc., Besins Healthcare, Inc., Besins Healthcare, S.A., Unimed Pharmaceuticals, LLC f/k/a Unimed

Pharmaceuticals, Inc. (hereinafter jointly “Defendants” or “AbbVie”), and the prescription drug Testopel, which is manufactured, sold, distributed and promoted by the Defendant Auxilium Pharmaceuticals, Inc. as testosterone replacement therapies.

2. Defendants misrepresented that AndroGel and Testopel are safe and effective treatments for hypogonadism and a condition they referred to as "low testosterone," when in fact the drugs cause serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. AndroGel and Testopel are exogenous forms of the androgen testosterone. They regulate the expression of platelet TXA_2 receptors in humans, which significantly increases platelet aggregation. They cause an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

4. AndroGel is delivered transdermally and is applied to the skin in the form of a gel. It is available in either a 1% or 1.62% concentration.

5. Testopel is an implantable testosterone pellet that is surgically inserted beneath the patient’s skin.

6. Defendants failed to adequately warn physicians about the risks associated with the AndroGel and Testopel and the monitoring required to ensure their patients’ safety.

7. Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for AndroGel and Testopel. Further, Defendants

engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low T", an abbreviated term for low testosterone.

8. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

9. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "LowT". Additionally, low testosterone is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

10. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially. This has directly related to AndroGel's sales increasing to over $1.37 billion per year and the sales of Testopel rising dramatically as well.

11. Consumers of AndroGel and Testopel and their physicians relied on the companies false representations and were misled as to the drugs' safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

12. At all times material hereto, Auxilium was a seller, producer, marketer, promoter, and distributor of Testopel, and utilized a nation-wide sales-force to detail, promote, and market

the Testopel product to physicians, pharmacies, third-party benefits payers and health insurers, and healthcare providers.

13. Testopel reached the Plaintiff, as a consumer and patient, from Auxilium in an unaltered condition through the stream of interstate commerce.

14. The Plaintiff was within the market to which Auxilium directed its product marketing, physician-detailing, advertising, and promotional sales strategies, initiatives, activities, and efforts.

15. Androgel and Testopel were approved by the FDA for the treatment of primary or secondary hypogonadism in men.

16. In fact, Defendants, along with other testosterone replacement therapy ["TRT"] manufacturers,[1] stated in the *Advisory Committee Industry Briefing Document Testosterone Replacement Therapy* (emphasis added) submitted to the FDA in advance of the September 17, 2014 Advisory Committee[2] hearing: "TRT Sponsors remain committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions."

17. At all times material hereto, despite being "committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions," AbbVie, Abbott, and Auxilium made no labelling changes to the AndroGel and Testopel labels concerning the risk of:

a. heart attacks and consequent myocardial damage;

[1] The "TRT Sponsors include AbbVie, Auxilium Pharmaceuticals, Inc., Besins Healthcare, Clarus Therapeutics, Eli Lilly and Company, Lilly USA, LLC, Endo Pharmaceuticals, Lipocine, MonoSol Rx, TesoRx, Trimel Pharmaceuticals, Upsher Smith Laboratories, and Viramal.

[2] Joint Meeting for Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSARM AC).

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae including, but not limited to, the requirement for anticoagulation and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

18. Hypogonadism is a medical disorder characterized by low testosterone levels caused by a congenital or acquired injury to or infection or pathological conditions of the male reproductive organs (testes); or pathologic conditions of the hormonal axis which regulates testosterone production by the male reproductive organs.

19. At all times material hereto, and since the time that the AndroGel and Testopel products were approved by the FDA, Defendants knew and understood the FDA-approved indications for clinical use of the AndroGel and Testopel products.

20. Androgens, in general, and AndroGel and Testopel, in particular, were only indicated for testosterone replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, with specific material limitations on the approved indications for clinical use confined to primary and secondary hypogonadism.

21. Defendants expanded the indications for use of the AndroGel and Testopel products by promoting and detailing “Low T” as an acquired form of hypogonadism.

B. PARTIES

22. Plaintiff is and was at all times relevant hereto, a resident and citizen of Indianapolis, IN.

23. Defendant AbbVie is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

24. Defendant Abbott Laboratories Inc. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbot Park Road, North Chicago, Lake County, Illinois 60064.

25. By way of background, Unimed Pharmaceuticals Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc. acquired Solvay's pharmaceutical division which included AndroGel. Then in 2013, Abbott created AbbVie, a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

26. Besins Healthcare, Inc. f/k/a Besins Iscovesco U.S., Inc., f/k/a Laboratories Besins-Iscovesco is a corporation organized and existing under the laws of the State of Delaware.

27. Upon information and belief, Besins Healthcare, Inc. has its principal place of business at 607 Herndon Parkway, Suite 201, Herndon, Virginia 20170.

28. Besins Healthcare, Inc. is, upon information and belief, a wholly-owned subsidiary of Besins Healthcare, S.A.

29. At all times relevant, Besins Healthcare, Inc. f/k/a Besins-Iscovesco U.S., Inc., f/k/a Laboratories Besins-Iscovesco developed the pharmaceutical formulation for AndroGel and had rights to sell AdroGel in the United States.

30. Besins Healthcare, S.A. is, upon information and belief, a privately held corporation with its headquarters in Bangkok, Thailand, at the following address: Besins Healthcare, S.A., 283/92 Home Place Office Building, 18th Floor Sukhumvit 55, Klong Ton Nua Wattana, Bangkok 10110, Thailand.

31. Besins Healthcare, S.A. is the parent company of Besins Healthcare Inc. f/k/a Besins-Iscovesco U.S., Inc., f/k/a Laboratories Besins-Iscovesco.

32. At all times relevant, Besins Healthcare, S.A. manufactured AndroGel for sale in the United States.

33. Unimed Pharmaceuticals, LLC, f/k/a Unimed Pharmaceuticals, Inc., is a limited liability company organized and existing under the laws of Delaware, with its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois, 60064.

34. Unimed Pharmaceuticals, LLC, f/k/a Unimed Pharmaceuticals, Inc., is a wholly owned subsidiary of AbbVie, Inc.

35. Upon information and belief, at all times relevant, Unimed Pharmaceuticals, LLC, f/k/a Unimed Pharmaceuticals, Inc., held rights pursuant to a licensing agreement to sell AndroGel in the United States.

36. At relevant times, Unimed Pharmaceuticals, LLC f/k/a Unimed Pharmaceuticals, Inc. marketed and sold AndroGel in the United States.

37. Unimed Pharmaceuticals, LLC is the registered owner of the trademark for AndroGel that is registered with the United States Patent and Trademark Office.

38. Defendant, Auxilium Pharmaceuticals, Inc. [“Auxilium”], is a corporation organized according to and existing under the laws of the State of Delaware, with headquarters and a principle place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087.

39. At all times material hereto, Auxilium produced and manufactured or contracted for the production and manufacture of Testopel pursuant to the May of 2000 licensing agreement with Bentley.

C. JURISDICTION AND VENUE

40. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

41. This Court has personal jurisdiction of the Defendants because AbbVie Inc., Abbott Laboratories Inc., and Unimed Pharmaceuticals, LLC, f/k/a Unimed Pharmaceuticals, Inc., have their primary place of business in Illinois and all Defendants have conducted substantial business in Illinois.

42. Venue is proper in this Court pursuant to Case Management Order No. 12, which permits the direct filing of Plaintiff's claims in this Court.

D. FACTUAL BACKGROUND

1. General Allegations

43. This action is for damages brought on behalf of the Plaintiff who was prescribed and supplied with, received and who has taken and applied the prescription drugs AndroGel and Testopel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

44. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

45. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drugs AndroGel and Testopel for the use and application by men, including, but not limited to, Plaintiff.

46. At all times herein mentioned, Defendants were authorized to do business within the states of Indiana and Illinois.

47. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

48. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the

medical profession that the drugs AndroGel and Testopel are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Regulatory History and Approved Uses

49. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

50. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

51. In men, testosterone levels normally begin a gradual decline after the age of thirty.

52. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

53. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders and other conditions which cause suppression of gonadotropin-releasing hormone (GnRH).

54. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men." The Defendant represented to the FDA that it would market and sell the drug to this patient population of one million men who have an actual diagnosis of hypogonadism with an associated medical condition. This was a false representation that it made to the FDA in order to obtain approval of the drug.

55. The Food and Drug Administration approved AndroGel 1% on February 28, 2000 for the treatment of adult males who have low or no testosterone (a condition called Hypogonadism) in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy. (AndroGel 1.62% was approved in April, 2011). After FDA approval, AndroGel was widely advertised and marketed by Defendant as a safe and effective testosterone replacement therapy.

56. In 2000, when the FDA approved AndroGel, the company announced that the market had increased from one million men to "four to five million American men." By 2003, the number again increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 - 2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription. A Canadian study showed that only about 6.3% of men who were prescribed testosterone actually met the diagnostic criteria for hypogonadism.

57. At all times material hereto, and since the time that AndroGel and Testopel first received approval from the FDA, the Defendants knew and understood the FDA-approved indications for clinical use of the AndroGel and Testopel products.

58. The FDA-approved indications for AndroGel and Testopel therapy did not include "reduced sexual function, desire and performance, low energy or fatigue, bad mood or poor concentration, reduced muscle mass/strength and increased body fat, which are often attributed to other conditions."

59. Hypogonadism is not defined medically as a failure to produce "enough" of the hormone testosterone within the body. Hypogonadism represents a well-defined array of medical diseases as described in the AndroGel and Testopel PPIs.

60. Defendants knew that "reduced sexual function, desire and performance, low energy or fatigue, bad mood or poor concentration, reduced muscle mass/strength and increased body fat, which are often attributed to other conditions" were not, and never have been, the FDA-approved indications for clinical use of the AndroGel and Testopel products.

61. Throughout their marketing and promotional campaigns to consumers and patients, Defendants misrepresented and mischaracterized the *normal* physiologic declines in testosterone levels observed in aging men and the age-related symptoms observed in men as being synonymous with the medical diagnosis of hypogonadism; and knowingly, falsely, deceptively, and inaccurately designated this contrived, invented, and medically unfounded form of "hypogonadism" as "Low T."

62. Defendants knowingly, falsely, deceptively, and inaccurately designated this contrived and invented disease as "Low T" medically designated it as a form of "hypogonadism" and a clinical indication for AndroGel and Testopel treatment.

63. Defendants obtained FDA approval for the AndroGel and Testopel products for the treatment of primary and secondary hypogonadism, and then engaged in aggressive "off-label" marketing and promotional campaigns which encouraged and drove "off-label" clinical use of AndroGel and Testopel.

64. Defendants sought to expand the patient populations treated with the AndroGel and Testopel products through false, deceptive, and misleading promotional activities, detailing, and marketing to physicians and healthcare providers.

65. Defendants knowingly, falsely, deceptively, and inaccurately educated and detailed physicians that AndroGel and Testopel were FDA-approved treatments of "Low T," and thereby engaged in "off-label" promotion and "label expansion."

66. Defendants knowingly, falsely, deceptively, and inaccurately educated and informed consumers, including the Plaintiff, through multi-platform national marketing and product awareness campaigns, that AndroGel and Testopel were FDA-approved for the treatment of "Low T."

67. Defendants knowingly, falsely, deceptively, and inaccurately promoted AndroGel and Testopel and testosterone replacement therapy for "Low T" by way of sponsored "thought-leaders," "key opinion leaders," sponsored speakers, and sponsored medical authors associated with Defendants. Through these individuals, Defendants advocated clinical uses for AndroGel and Testopel that exceeded the FDA-approved parameters, including the population of patients for whom testosterone therapy was appropriate.

68. Defendants' statement that Androgel and Testopel are "used to treat adult males with low or no testosterone" is false, deceptive, and misleading, and fails to disclose material medical information, including the FDA-approved uses for the AndroGel and Testopel product.

69. AndroGel and Testopel were specifically approved by the FDA for the treatment of primary and secondary hypogonadism, which are a well-defined set of pathologic diagnoses with specific diagnostic criteria and underlying pathologic findings.

70. At all times material hereto, Defendants knowingly failed to state that the AndroGel and Testopel products were not indicated for use by men with age-related declines in testosterone levels and age-related symptoms; that these were not FDA-approved indications for clinical use of the AndroGel and Testopel products; and that men with these conditions are not appropriate or approved candidates for treatment with the Androgel and Testopel products.

71. Defendants knew that the FDA had not approved the AndroGel and Testopel products for the treatment of:

a. decreased sexual motivation;

b. decreased spontaneous erections;

c. decreased sexual desire;

d. decreased lean body mass (muscle);

e. increased body fat; or

f. increased fat mass.

72. Defendants promoted and detailed the AndroGel and Tesopel products for the treatment of:

a. decreased sexual motivation;

b. decreased spontaneous erections;

c. decreased sexual desire;

d. decreased lean body mass (muscle);

e. increased body fat; and

f. increased fat mass.

73. This represented "off-label" marketing, promotion, detailing, and recommended clinical use of the AndroGel and Testopel products by Defendants.

74. Defendants promoted and detailed these "off-label" clinical uses to physicians, consumers, and patients.

75. Defendants knew that the following clinical indications for use represented "off-label" promotion and detailing for AndroGel and Testopel:

a. decreased sexual motivation;

b. decreased spontaneous erections;

c. decreased sexual desire;

d. decreased lean body mass (muscle);

e. increased body fat; or

f. increased fat mass.

76. Defendants undertook to provide diagnostic information and criteria to the consuming public and to patients concerning the signs and symptoms of "Low T," which Defendants implicitly and explicitly represented to consumers and patients as a condition synonymous with hypogonadism.

77. Defendants promoted indications for the clinical use of the AndroGel and Testopel product for a diagnosis, "Low T," that did not constitute a diagnosis of hypogonadism or an indication for AndroGel and Testopel therapy.

78. Defendants expressly warranted and represented to consumers and patients that AndroGel and Testopel were FDA-approved treatments for "Low T" and age-related symptoms

in men, and that AndroGel and Testopel had favorable clinical safety and effectiveness profiles for the treatment of “Low T” and age-related symptoms in men.

79. Defendants impliedly warranted and represented to consumers and patients that AndroGel and Testopel were FDA-approved treatment for “Low T” and age-related symptoms in men, and that AndroGel and Testopel had favorable clinical safety and effectiveness profiles for the treatment of “Low T” and age-related symptoms.

80. These representations were a “basis of the bargain” upon which consumers and patients, including the Plaintiff, justifiably relied in their choice to purchase, administer, and continue to administer the AndroGel and Testopel products.

3. Direct to Consumer Marketing and Promotion to Physicians for Unbranded/Off-Label Use.

81. Defendants expanded the indications for use by promoting and detailing “Low T” as an acquired form of hypogonadism, and advantaged intentional ambiguity in the AndroGel and Testopel products labeling as a basis for “label expansion” and “off-label” marketing, detailing, and promotion to physicians.

82. In 2000, when reviewing the drug's advertisements, the FDA told AndroGel makers that "claims and representation that suggest that AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." The drug, the FDA said, was only approved for men with hypogonadism. Despite this admonition from the FDA, the Defendants continued to market and promote testosterone replacement therapy for “andropause” and “LowT”.

83. AndroGel Defendants coordinated a massive advertising campaign targeted toward men who did not have hypogonadism, nor had low or no testosterone in conjunction with

an associated medical condition. The direct to consumer marketing was designed to convince men that they suffered from a non-existent and unrecognized medical condition called “LowT”, which was a term for low testosterone. AndroGel Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

84. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

85. AndroGel Defendants’ national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", “Are you sad and/or grumpy?”, and “Do you have a lack of energy?”

86. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The

pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013, N.Y. TIMES.

87. Since the FDA approved AndroGel and Testopel for a very specific medical condition called hypogonadism, Defendants have also sought to convince primary care physicians that hypogonadism is synonymous with "LowT" and that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

88. While running its disease awareness campaign, AndroGel Defendants promote their products as an easy to use topical testosterone replacement therapy. AndroGel Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

89. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

90. The Defendant manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "LowT", which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the

Defendant marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

91. A 2004 memo on AndroGel sales strategies said the sales force was putting extra emphasis on rural areas, since "rural doctors are typically very accessible, give us plenty of time to teach them the right way to diagnose and treat, and they have the patients."

92. AndroGel Defendants successfully created a robust and previously nonexistent market for their drugs. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

93. As observed by Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. in their article "Low T as a Template: How to Sell Disease" published in JAMA Internal Medicine 173(15):1460-1462 (August 12/26, 2013) concerning the "Low T" campaigns by the pharmaceutical industry:

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

94. AndroGel Defendants' advertising paid off in a return of $1.4 billion in sales during the past year (2013), making AndroGel the biggest selling androgen drug in the United

States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

95. In 2009, a whistle-blower lawsuit filed by relator John King and Jane Doe on behalf of the United States and 23 individual states alleged that AndroGel was marketed and promoted for off-label uses, including osteoporosis, sexual dysfunction, depressions and obesity.

96. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. *See* Singer, *Selling That New-Man Feeling*, *supra*; See *also*, Larry Dobrow, *All-star large pharma marketing team of the year: Androgel*. Jan. 2, 2013, Medical Marketing & Media, *available at:* http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/.

97. The Defendants engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "LowT".

98. The marketing program sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that the use of AndroGel and Testopel are safe for

human use as a treatment for "LowT", even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

99. At all times material hereto, Defendants' marketing strategy included the use of sales or drug detailing representatives ["reps"] and marketing and brand team personnel who performed on-line and in-person AndroGel and Testopel products detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

100. The Defendants' drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the AndroGel and Testopel products, as well as discount and/or rebate coupons to give to patients for the purchase of AndroGel and Testopel.

101. Defendants' drug "reps" detailed and marketed AndroGel and Testopel to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

102. Defendants denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

103. The Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

104. The Defendants knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

105. Defendants marketed, promoted, and detailed AndroGel and Testopel for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the AndroGel and Testopel products.

106. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

107. A manufacturer misbrands a drug if the labeling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

108. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

109. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

110. The FDA did not, and never has, approved AndroGel and Testopel for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or,

g. bone strength or density abnormalities.

111. In 2003, Auxilium developed a marketing strategy to increase consumer and physician targeting and to achieve greater sales efficiencies by working with educational groups, including "Everyday Health," "Hormone.org," and "MensHealthNetwork."

112. Defendants, recruited and engaged a cadre of "thought leaders," "key opinion leaders," and industry funded speakers, including individuals with leadership positions in influential scientific organizations and societies (e.g., the Endocrine Society and the American Urological Association) to offer opinions which supported, advocated, and encouraged "off-label" clinical indications for testosterone therapy in general, including therapy with the AndroGel and Testopel products.

113. Defendants engaged "thought-leaders," "key opinion leaders," and medical consultants, including Dr. Abraham Morgantaler from Harvard University, who was a member of Auxilium's Scientific Advisory Board; and Dr. Francis Hayes from Harvard University and the Massachusetts General Hospital, who was a co-author of the 2010 Endocrine Society testosterone guidelines, *Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline*, to influence physicians concerning the diagnosis of "Low T" and the benefits of testosterone replacement therapy for the treatment of age-related declines in testosterone levels and age-related symptoms in men. These physicians aggressively condoned and advocated "off-label" and unapproved uses for the AndroGel and Testopel products.

114. At all times material hereto, Defendants conducted "off-label" detailing and promotion of Androgel and Testopel to physicians, and misrepresented to physicians that

Androgel and Testopel were an FDA-approved treatment for "Low T" and age-related declines in testosterone levels and age-related symptoms in men.

115. Defendants failed to disclose to physicians that the FDA had not approved Androgel and Testopel for the treatment of age-related declines in testosterone levels or age-related symptoms in men.

116. At all times material hereto, Defendants knew and understood that the male aging process is not an acquired form of hypogonadism, and that declines in testosterone levels are a physiologic response during male aging.

117. At all times material hereto, Defendants made false, deceptive, inaccurate, and misleading statements and claims to physicians and healthcare providers regarding the clinical safety and effectiveness profiles of AndroGel and Testopel, and their spectrum of FDA-approved indications for clinical use.

118. At all times material hereto, Defendants failed to warn physicians and healthcare providers of the known risks of cardiovascular, thromboembolic and cerebrovascular injuries causally related to the use of the AndroGel and Testopel products.

119. Defendants represented that they had designed and conducted clinical trials to provide prescribing physicians with comprehensive information regarding the clinical safety and effectiveness profiles of AndroGel and Testopel; and with information concerning the benefits of AndroGel and Testopel use. This was false and misleading.

120. Defendants never informed the FDA that they engaging in "label expansion" or "off-label" promotion of the AndroGel and Testopel products via its marketing and promotion to patients and consumers.

121. Defendants never informed the FDA that it was engaging in "label expansion" or "off-label" promotion and detailing of the AndroGel and Testopel products to physicians and healthcare providers.

122. At all times material hereto, Defendants owed a duty to prescribing physicians to inform these physicians of the approved uses for the AndroGel and Testopel products, and to warn prescribing physicians that the FDA had not approved AndroGel and Testopel for the treatment of age-related declines in testosterone levels and age-related symptoms in men.

123. At all times material hereto, Defendants had a duty to warn physicians that AndroGel and Testopel were being promoted for "off-label" indications for clinical use, and that there were no appropriately developed and controlled data, studies, or investigations to support these clinical uses.

124. At all times material hereto, Defendants knowingly misinformed physicians, including Plaintiff's prescribing physician, concerning the FDA-approved uses for AndroGel and Testopel and the approved clinical indications for AndroGel and Testopel therapy.

125. At all times material hereto, Defendants knowingly and deceptively misinformed physicians, including Plaintiff's prescribing physician, concerning the clinical safety and effectiveness profiles of the AndroGel and Testopel products via product labelling, detailing and promotion, and articles in the medical literature written by sponsored authors.

126. At all times material hereto, Defendants intentionally sought to simultaneously:

a. on the one hand, deceive and confuse consumers and patients concerning the indications for clinical use of the AndroGel and Testopel products; the definition of "Low T" and its clinical diagnostic criteria; the medical

condition and definitions of hypogonadism; and the clinical safety and effectiveness profiles of AndroGel and Testopel; while

b. on the other hand, knowingly, willfully, and deceptively promoting, detailing, and marketing the AndroGel and Testopel product to physicians for "off-label" use.

127. These combined and concerted actions and activities were undertaken by Defendants to drive consumer demand for testosterone replacement therapy for "Low T" with AndroGel and Testopel, while simultaneously positively influencing an increase in the AndroGel and Testopel prescribing habits of physicians.

128. At all times material hereto, Defendants disseminated and provided information during the promotion and detailing of AndroGel and Testopel to healthcare providers, including Plaintiff's prescribing physician, which failed to disclose the correct and accurate FDA-approved indications for use of AndroGel and Testopel.

129. The information provided to AndroGel and Testopel prescribing physicians was, and remains, false and misleading, and fails to warn that the AndroGel and Testopel products were being promoted for "off-label" indications for use for which clinical safety and effectiveness profiles are lacking.

130. At all times material hereto, Defendants had a continuing duty to correct the known misinformation which it had disseminated concerning the FDA-approved indications for use of the AndroGel and Testopel product, including the lack of clinical safety and effectiveness profiles for AndroGel and Testopel.

131. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of the AndroGel and Testopel product to heart attack, stroke,

deep vein thrombosis and its life- and limb-threatening sequelae, pulmonary embolism, and sudden cardiac death.

132. At all times material hereto, Defendants misbranded the AndroGel and Testopel products on an on-going and continuous basis, and failed to warn physicians and patients that AndroGel and Testopel was not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

133. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with AndroGel and Testopel use, which were foreseeable at the time of product launch.

134. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for AndroGel and Testopel, including Plaintiff's prescribing physician. Specifically, the FDA had not approved AndroGel and Testopel or any other testosterone-containing preparation for the treatment of "Low T."

135. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted the testosterone-containing product AndroGel and Testopel with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

136. At all times material hereto, Defendants sought to conflate the diagnosis of hypogonadism with the "diagnosis" of "Low T" through the activities of drug sales "reps," promotional and branding teams, and marketers who were detailing, promoting, and marketing Androgel and Testopel to physicians and healthcare providers, including Plaintiff's prescribing physician. These activities were undertaken to falsely promote AndroGel and Testopel as FDA-approved treatments for "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

137. Defendants knowingly and intentionally deceived consumers and patients, via consumer symptom-tracking quizzes, the "Interactive ADAM Questionnaire," and "relationship marketing emails," to the belief that they harbored or suffered from a form of hypogonadism necessitating diagnostic evaluation, testing, and treatment with the AndroGel and Testopel products.

138. In the *Auxilium 2012 Annual Report* to investors, Auxilium stated that "the U.S. market will continue to expand based on disease education programs and increasing patient disease awareness, driven in part by national 'direct-to-consumer' television and Internet advertising campaigns focused on adult males with low testosterone."[3]

139. Age-related declines in men's testosterone levels and age-related symptoms are not categorized as a "disease" for which AndroGel and Testopel was an FDA-approved indication for clinical use.

140. At all times material hereto, Defendants undertook to educate consumers and patients, including the Plaintiff, concerning "Low T" as a "disease" by providing specific misinformation regarding the diagnosis and treatment of "Low T," and portraying "Low T" as a "disease" subsumed under the medical category of acquired hypogonadism. This was undertaken in a concerted effort to drive treatment-demand and increase physician prescribing habits for the AndroGel and Testopel product for the economic and financial benefit of Defendants.

141. At all times material hereto, Defendants undertook a duty of care to provide accurate, truthful, correct, and appropriate information about hypogonadism and the FDA-

[3] *Auxilium 2012 Annual Report* ("Fully Maximize Value of Current Portfolio").

approved uses of Androgel and Testopel to consumers and patients, including the Plaintiff, to ensure the safety and well-being of the consuming public and patients.

142. The treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms created a manifest and unreasonable public health hazard, including a hazard to the Plaintiff, because patients with "Low T" should not have been exposed to treatment with the AndroGel and Testopel products.

143. Through the promotion, detailing, and marketing of the AndroGel and Testopel product as a treatment for age-related declines in testosterone levels and age-related symptoms in men, Defendants exposed men to "a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels."[4]

144. Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that they provided to consumers and patients through their multi-platform marketing, promotional, educational, and awareness campaigns concerning the AndroGel and Testopel product and their indications for clinical use.

145. Defendants further knew that consumers and patients would make treatment choices and exercise their treatment options about their use of the AndroGel and Testopel products in reliance upon safety and effectiveness information provided to them by Defendants.

146. In 2012, Auxilium "[c]arefully targeted sales and marketing efforts aimed at the most productive segment of the TRT market—17,000 high volume prescribing physicians who account for approximately 51% of all gel TRT prescriptions."[5]

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[4] Schwartz, L.M. and Woloshin, S. (August 12/26, 2013). Low T as a Template: How to Sell Disease. *JAMA* 173(15):1460-1462

[5] *Auxilium 2012 Annual Report* ("Fully Maximize Value of Current Portfolio").

147. AndroGel and Testopel were marketed, promoted, and detailed to physicians by Defendants and by others on behalf of AbbVie, Abbott, and Auxilium, with the intent that the product reach the Plaintiff, and be prescribed to the Plaintiff for "off-label" use by his prescribing physician.

148. As marketed, detailed, and promoted to physicians, including the Plaintiff's prescribing physician, Defendants failed to warn that AndroGel and Testopel caused or increased the risk of harm of cardiovascular and cerebrovascular injuries, including myocardial infarction and cerebrovascular accident, pulmonary embolism, deep vein thrombosis and its life- and limb-threatening sequelae, and sudden cardiac death.

149. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of AndroGel and Testopel to cause, or increase the harm of other severe bodily injuries, including myocardial infarction, cerebrovascular accident, deep vein thrombosis and its life- and limb-threatening sequelae, pulmonary embolism, and sudden cardiovascular death.

150. At all times material hereto, and currently, Defendants failed to warn physicians, healthcare providers, patients, and consumers of the risks of cardiovascular events and cerebrovascular accident caused by or increased in the risk of harm by the AndroGel and Testopel products.

151. AndroGel and Testopel should not have been designed for the treatment of age-related declines in testosterone levels and age-related symptoms or the treatment of "Low T," and should not have been promoted for, prescribed for, marketed for, or used for this purpose.

152. At all times material hereto, safer alternatives to AndroGel and Testopel existed for the treatment of age-related symptoms which were approved for use for these conditions, including pharmaceutical and non-pharmaceutical treatments for weight loss, depression, mood disorders, decreased muscle mass, increased fat mass, decreased bone density, and erectile dysfunction.

153. AndroGel and Testopel were negligently designed for the treatment of "Low T."

154. At all times material hereto, Defendants provided information to physicians via physician promotion and detailing, "ePromotion," PPIs, the Physician's Desk Reference, sponsored "thought-leader," "key opinion leader," and funded speaker statements, sponsored medical literature authorship, and marketing which failed to warn of the cardiovascular and cerebrovascular risks of AndroGel and Testopel use.

155. At all times material hereto, Defendants failed to inform physicians, including the Plaintiff's prescribing physician, that AndroGel and Testopel was not approved by the FDA "for the treatment of age-related symptoms or age-related decline in testosterone levels."

156. Additionally, Defendants knowingly and deceptively encouraged and detailed physicians to prescribe AndroGel and Testopel for "off-label" use, including the treatment of "Low T" and age-related declines in testosterone levels and age-related symptoms, with actual knowledge that the AndroGel and Testopel product was not approved by the FDA for these indications for use.

157. Defendants undertook to provide consumers with specific medical educational and informational materials concerning the indications for seeking treatment for "Low T" with AndroGel and Testopel, when in fact "Low T" was not an indication for AndroGel and Testopel therapy.

158. Defendants assumed a duty of care to inform and educate consumers about the approved uses of AndroGel and Testopel, as well as the risks, benefits, safety, and effectiveness profiles of AndroGel and Testopel therapy, to ensure the safety and well-being of AndroGel Testopel users, including the Plaintiff.

159. Defendants undertook to inform and educate consumers about the diagnostic hallmarks of "Low T," and engaged in and encouraged mass consumer screening for "Low T" via patient-directed questionnaires, quizzes, and information, as part of a mass marketing effort to encourage patients to seek treatment for "Low T," while having actual knowledge that AndroGel and Testopel were not indicated for the treatment of "Low T," nor was it proven to be clinically safe and effective for treating "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

160. The Plaintiff reasonably and justifiably relied to his detriment on the fraudulent representations, negligent misrepresentations, misinformation, deceptive statements, and express and implied warranties made by or provided by Defendants with respect to the AndroGel and Tesopel products.

161. The Plaintiff would not have sought or continued treatment for "Low T" or administered AndroGel and Testopel had he been provided with adequate, true, accurate, and correct information by Defendants about the risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events causally associated with the use of AndroGel and Testopel, and the fact that "Low T" was not an FDA-approved indication for the clinical use of AndroGel and Testopel.

162. The Plaintiff would not have sought or continued treatment for "Low T," or administered AndroGel and Testopel, had he been provided with adequate, true, accurate, and

correct information by Defendants, including information that there were no proven clinical profiles of safety or effectiveness for the use of AndroGel and Testopel to treat "Low T."

163. Defendants coordinated a comprehensive national consumer and patient awareness and educational campaign crafted to convince men that non-specific and generalized symptoms of the aging process, and age-related declines in testosterone levels, were a "disease" known as "Low T" that could or should be treated with AndroGel and Testopel as an appropriate treatment option.

164. A decrease in testosterone levels is a physiologic and expected component of the normal male aging process, and is neither a "disease" nor "condition" as described by Defendants.

165. The information provided by Defendants concerning testosterone levels in aging men knowingly, deceptively, and deliberately ignored multiple longitudinal and cross-sectional studies of normal men which demonstrated that a decrease in testosterone levels as a physiologic component of the male aging process.

166. Defendants repeatedly and knowingly misrepresented, through comprehensive national direct-to-consumer educational and awareness campaigns, that "Low T" was a pathologic "disease" requiring treatment, and that "Low T" was synonymous with primary or secondary hypogonadism.

167. Defendants deceptively advocated and promoted the treatment of "Low T" as equivalent to the treatment of primary or secondary hypogonadism, which was "label expansion" and misbranding.

168. During the detailing, marketing, and promotion to physicians, Defendants who were detailing AndroGel and Testopel on behalf of Defendants never warned physicians,

including Plaintiff's prescribing physician, that AndroGel and Testopel caused or increased the risk of harm of adverse cardiovascular and cerebrovascular events.

169. Defendants, through their national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs, undertook to inform the consuming public and patients, including the Plaintiff, about a "disease" Defendants denominated and characterized as "Low T."

170. These materials did reach the Plaintiff, and he justifiably relied upon these materials in reaching his decision to purchase, use, and continue the use of AndroGel and Testopel throughout his course of testosterone therapy.

171. The Plaintiff would not have taken AndroGel or Testopel had the educational and informational materials made available to him by Defendants, and upon which he relied to his detriment, informed him about the risks of thromboembolic events, cardiovascular events and cerebrovascular accident with product use.

172. The warnings accompanying the AndroGel and Testopel products, upon which the Plaintiff's physician relied, did not reasonably warn of the risks of the serious adverse life- and limb-threatening thromboembolic, cardiovascular and cerebrovascular events causally associated with testosterone therapy.

173. In 2004, Auxilium targeted the population of older men who manifested age-related declines in testosterone levels as a component of the aging process, and coincident age-related symptoms as set forth on the "Interactive ADAM Questionnaire," as fodder for the promotional and marketing campaigns for "Low T" and the Testopel product.

174. The standard treatment for age-related declines in testosterone levels and age-related symptoms in men is not testosterone therapy. These conditions are not subsumed under

nor do they meet the definition of hypogonadism as set forth in the FDA-approved clinical indications for AndroGel and Testopel use.

175. Increasing testosterone levels via the administration of exogenous testosterone in men experiencing age-related declines in testosterone levels and age-related symptoms of "low energy levels, loss of sex drive, decreased muscle mass and mild depression" are not FDA-approved clinical indications for use of AndroGel and Testopel, and reflects and represents the "off-label" promotion and use of AndroGel and Testopel, and "label expansion" for AndroGel and Testopel use.

176. Such uses of the AndroGel and Testopel product create unreasonable and foreseeable health hazards, and created a physiologic milieu in men which causes or increases the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae including but not limited to, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

177. Exposure of men to these health hazards and risks was unwarranted, and reflected consumer and patient exploitation through the reckless, wanton, deceptive, and fraudulent promotion and marketing of non-approved indications for AndroGel and Testopel prescription and use.

178. Defendants sought to raise the awareness of physicians, including the Plaintiff's prescribing physician, with respect to a condition denominated as "Low T," and to educate physicians about "Low T" and its treatment.

179. Defendants had a duty to warn prescribing physicians about the risks of AndroGel and Testopel use, including the risks of cardiovascular events and cerebrovascular accident.

180. In fact, in 2004, instead of warning physicians about the increased risk of cardiovascular disease reported with the use of testosterone replacement therapy, Defendants instead warned potential investors by way of its Form S-1 Registration Statement submitted to the Securities and Exchange Commission:

> Recent studies of female hormone replacement therapy products have reported an increase in health risks. As a result of such studies, some companies that sell or develop female hormone replacement products have experienced decreased sales of these products, and in some cases, a decline in the value of their stock. Publications have, from time to time, suggested potential health risks associated with testosterone replacement therapy. Potential health risks were described in a 2002 article published in *Endocrine Practice* and a 1999 article published in the *International Journal of Andrology*. The potential health risks detailed were fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, increased cardiovascular disease risk and the suppression of sperm production. It is possible that studies on the effects of TRT could demonstrate these or other health risks.

4. Adverse Events and Serious Health Risks Caused by TRT.

181. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

182. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal

absorption into the body. It can also be delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

183. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[6] and serum estradiol levels[7]. It can also cause increased platelet aggregation and vasoconstriction.

184. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

185. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[8] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

186. The clinical trial data submitted to the FDA for the approval of AndroGel showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that

[6] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.

[7] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[8] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

187. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[9] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

188. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[10]

189. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after

[9] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

[10] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[11]

190. In yet another large, prospective study[12] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

191. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[13] An increase in blood viscosity is a known risk factor for ischemic heart disease[14], and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

192. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is

[11] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.
[12] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.
[13] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.
[14] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

converted by the body (aromatized) to estradiol.[15] The increase of estradiol is in direct relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[16]

193. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[17] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

194. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[18]

195. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol

[15] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.

[16] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[17] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.

[18] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in middle-aged men."[19] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

196. In a case control study of men in the Framingham cohort *supra*, serum estradiol levels were significantly increased in subjects with coronary heart disease.[20]

197. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol. [21] Impaired contractile function results in numerous cardiovascular injuries and disease.

198. A study published in 2007 compared blood levels of testosterone and *estradiol* in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of *estradiol* in both groups of heart attack patients compared with

[19] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.

[20] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.

[21] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

those without coronary disease.[22] In another study, men admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients, *estradiol* levels in these heart attack patients were **180%** higher, while bioavailable testosterone levels were **nearly three times less** than those of control patients.[23]

199. High testosterone levels enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after MI, and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.[24]

200. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2has been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[25]

201. Thromboxane A2 is a potent vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease.

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[22] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.

[23] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.

[24] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory PhysiologyPublished 1 May 2006**Vol.** 290**no.** H2043-H2050**DOI:** 10.1152/ajpheart.01121.2005

[25] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

202. Thromboxane A2 is produced by activated platelets and has prothrombotic properties: It stimulates activation of new platelets as well as increases platelet aggregation.

203. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

204. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

205. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

206. In a study published in 2013[26], based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy among men lasting 12+ weeks reporting cardiovascular-related events, two reviewers independently searched, selected and assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased

[26] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

207. On July 8, 2010, Dr. W.J. Bremner published an editorial in the *New England Journal of Medicine* entitled "Testosterone Deficiency and Replacement in Older Men",[27] observing:

> The diagnosis of testosterone deficiency in older men is complicated by the fact that many older men (more than 20% in some studies) have testosterone levels that are lower than the normal range in younger men. In addition, the clinical presentation of male hypogonadism is nonspecific and overlaps with that of other illnesses and with the aging process itself. Therefore, it is frequently unclear in caring for individual older patients whether the diagnosis of hypogonadism is appropriate and whether testosterone administration might be helpful or might instead cause adverse effects.

208. Two observational studies have prompted the FDA to investigate the risk of adverse cardiovascular events associated with testosterone replacement therapy.

209. The Vigen Study identified a 30% increase in the risk of heart attack, stroke, or death in the study group prescribed testosterone therapy when compared to a group that did not receive testosterone replacement therapy.

210. The results of this study led Dr. Anne R. Cappola to observe:

> In light of the high volume of prescriptions and aggressive marketing by testosterone manufacturers, prescribers and patients should be wary. There

[27] *N Engl J Med* 363(2):189-191.

> is mounting evidence of a signal of cardiovascular risk, to which the study by Vigen et al. contributes. This signal warrants both cautious testosterone prescribing and additional investigation.[28]

211. The Finkle Study reported a two-fold increase in the risk of heart attack in men 65 years of age and older in the first 90 days following their first testosterone prescription. In men less than 65 years of age who harbored a pre-existing history of heart disease, the Finkle Study reported a two- to three-fold increased risk of heart attack in the first 90 days following a first prescription.

212. Testosterone replacement therapy results in the potential increase in hematocrit[29] and serum estradiol level.[30]

213. Testosterone administration is associated with suppression of serum hepcidin.

214. Increases in hematocrit in older men during testosterone therapy are related to the greater effect of suppression of hepcidin. "Testosterone administration is associated with suppression of serum hepcidin. Greater increases in hematocrit in older men during testosterone therapy are related to greater suppression of hepcidin." [31]

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[28]Cappola, A.R. (2013). Editorial: Testosterone Therapy and Risk of Cardiovascular Disease in Men. *JAMA* 310(17):1805-1806.

[29]Fernández-Balsells, M.M, Murad, M.H., Lane, M. *et al.* (2010). Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. *J Clin Endocrin Metab* 95(6):2560–2575; *see also* Bachman, E., Travison, T., Basaria, S. *et al.* (2013). Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. *J Gerontol A Biol Sci Med* at http://jmh.sagepub.com/content/early/2014/02/19/1557988314522642.full.pdf+html.

[30]Finkelstein, J.S., Lee, H., Burnett-Bowie, S.M. *et al.* (2013). Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men, *N Eng J Med* 369:1011-22.

[31] Eric Bachman, E., Feng, R., Travison, T., *et al.* (2010). Testosterone Suppresses Hepcidin in Men: A Potential Mechanism for Testosterone-Induced Erythrocytosis. *J Clin Endocrinol Metab* 95: 4743–4747.

215. Additionally, testosterone effects the expression of platelet thromboxane A2 receptors. The latter significantly increases platelet aggregation,[32] leading to a state of hypercoagulability.

216. Increases in hematocrit and estradiol are associated with hyperviscosity and hypercoagulability syndromes, and well-known risks of thrombosis leading to adverse cardiovascular and cerebrovascular ischemic events.[33]

217. In 1968, W. Fried and C.W. Gurney published an article in the *Annals of the New York Academy of Sciences* entitled "The Erythropoietic-Stimulating Effects of Androgens"[34] in which these authors described the capacity of androgenic steroids to induce erythrocytosis. "Drastic elevations of hematocrit may be detrimental to patients with underlying coronary, cerebral or peripheral vascular disease by possibly causing an increase in blood viscosity and increased risk of thrombosis."[35]

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[32] Ajayi, A.A., Mathur, R., Halushka, P.V. (1995). Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. *Circulation* 91: 2742-2747.

[33]Wannamethee, G., Perry, I.J., Shaper, A.G. (1994). Haematocrit, hypertension and risk of stroke. *J Intern Med* 235(2):163-8; *see also* Coglianese, E., Qureshi, M.M., Vasan, R.S. *et al.* (2012). Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. *Am J Cardiol* 109(2): 241–245; Braekkan, S.K., Mathiesen, E.B., Njølstad, I. *et al.* (2010). Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. *Haematologica* 95(2):270-5; Cinar,Y., Demir, G., Paç, M. *et al.* (1999). Effect of hematocrit on blood pressure via hyperviscosity. *Am J Hypertens* 12(7):739-43; Glueck, C.J., Friedman, J., Hafeez, A., *et al.* (2014). Testosterone, thrombophilia, thrombosis. *Blood Coagul Fibrinolysis* 25 (ePub ahead of print); Glueck, C.J., Richardson-Royer, C., Schultz, R. *et al.* (2014). Testosterone, thrombophilia, thrombosis. *Clin Appl Thromb Hemost* 20(1):22-30.

[34]*Ann NY Acad Sci* 149:356–365.

[35]Stergiopoulos, K., Brennan, J.J., Mathews *et al.* (2008). Anabolic Steroids, Acute Myocardial Infarction and Polycythemia: A Case Report and Review of the Literature. *Vascular Health and Risk Management* 4(6) 1475–1480.

218. An elevated hematocrit is an independent risk factor for adverse cardiovascular events.[36]

219. The *Framingham Heart Study* demonstrated a strong, graded relationship between hematocrit level and the risk of developing congestive heart failure.[37] In 3,523 *Framingham Heart Study* participants aged 50 to 65 years who were free of a history of heart failure at baseline, and who were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had nearly double the risk of new-onset heart failure during follow-up.[38]

220. An additional study using *Framingham Heart Study* data demonstrated that in lifetime nonsmokers, those in the highest hematocrit category (>45.0 for women, >49.0 for men) had greater than twice the risk for heart failure.[39]

221. The relationship between hematocrit level and cardiovascular risk is mediated by erythropoietin (EPO). Overexpression of the EPO gene in in-bred mice results in extremely high hematocrit levels and leads to increased cardiac weight, left ventricular dilation, and decreased survival compared to wild-type mice.[40]

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[36] *See* Coglianese, E., Qureshi, M.M., Vasan, R.S. *et al.* (2012), *supra* at f.n.19; *see also* Kunnas, T., Solakivi,T., Huuskonen, K. *et al.* (2009). Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. *Prev Med* 49 (1):45–47 (In this study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.).

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] Wagner, K.F., Katschinski, D.M., Hasegawa, J. *et al.* (2001). Chronic inborn erythrocytosis leads to cardiac dysfunction and premature death in mice overexpressing erythropoietin. *Blood* 97:536–542.

222. An elevated hematocrit among users of exogenously administered testosterone results from an elevation in EPO levels. This effect is most pronounced at 1 and 3 months following initial treatment.[41]

223. EPO can also activate platelets, causing an enhanced risk of thrombosis as shown in patients receiving exogenous EPO who have underlying cardiovascular diseases.[42]

224. Elevated EPO and its effect on hematocrit has been positively correlated with an increased risk of developing heart failure, even after adjusting for conventional heart failure risk factors.[43]

225. Elevated estradiol levels are also an independent risk factor for adverse cardiovascular events.[44,45,46]

226. A 1995 study demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response. This contributes to the thrombogenicity of androgenic steroids such as testosterone.[47]

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[41] *See* Bachman, E., Travison, T., Basaria, S. *et al.* (2013), *supra* at f.n. 16.

[42]Smith, K.J., Bleyer, A.J., Little, W.C. *et al.* (2003). The Cardiovascular Effects of Erythropoietin. *Cardiovasc Res* 59:538-548.

[43] Coglianese, E .E., Qureshi, M.M., Vasan, R.S. *et al.* (2012). Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. *Am J Cardiol* 109(2): 241–245.

[44] Khader, Y.S., Rice, J., John, L. *et al.* (2003). Oral contraceptives use and the risk of myocardial infarction: a meta-analysis. *Contraception 68*(1):11-17; *see also* Baillargeon, J.P., McClish, D.K., Essah, P.A. *et al.* (2005). Association between the current use of low-dose oral contraceptives and cardiovascular arterial disease: a meta-analysis. *J Clin Endocrinol Metab* 90(7):3863-3870 .

[45] Mohamad, M.J., Mohammad, M.A., Karayyem, M. *et al.* (2007). Serum Levels of Sex Hormones in Men with Acute Myocardial Infarction. *Neuro Endocrinol Lett* 28(2):182-6.

[46] Jankowska, E.A., Rozentryt, P., Ponikowska, B. *et al.* (2009). Circulating Estradiol and Mortality in Men with Systolic Chronic Heart Failure. *JAMA* 301(18):1892-1901.

[47] *See, e.g.*, Schrör, K., Morinelli, T.A., and Masuda, A. (1994). Testosterone treatment enhances thromboxane A2 mimetic induced coronary artery vasoconstriction in guinea pigs. *European Journal of Clinical Investigation* 24 (Suppl. 1):50-52; *see also* Adesuyi A. L. Ajayi, A., Mathur, R. *et al.* (1999). Testosterone Increases Human Platelet Thromboxane A_2 Receptor Density and Aggregation Responses. *Circulation* 91**:** 2742-2747.

227. Thromboxane A2 has been implicated in a range of cardiovascular diseases secondary to its acute and chronic effects on platelet aggregation, vasoconstriction, and vascular endothelial proliferation. In vitro, animal and human studies have established the central role of thromboxane A2 in cardiovascular disease.[48]

228. "Low-T" is a distinct and separate entity from the conditions for which testosterone replacement therapy has been FDA-approved; namely, for the conditions of primary hypogonadism and secondary hypogonadism.

229. On January 31, 2014, the FDA announced an investigation into the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products.[49]

230. In 2010, S. Basaria, A.D. Coviello, T.G. Travison et al. published an article in the *New England Journal of Medicine* entitled "Adverse Events Associated with Testosterone Administration."[50] ["Basaria Paper"].

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[48] *See* Katugampola, S.D. and Davenport, A.P. (2001). Thromboxane receptor density is increased in human cardiovascular disease with evidence for inhibition at therapeutic concentrations by the AT1 receptor antagonist Losartan. *Br J Pharmacol* 134:1385–1392; *see also* Cheng, Y., Austin, S.C., Rocca, B. *et al.* (2002). Role of prostacyclin in the cardiovascular response to thromboxane A2. *Science* 296:539–541 (Demonstrating the reciprocal relationship between thromboxane and prostacyclin *in vivo*); Kobayashi, T., Tahara, Y., Matsumoto, M. *et al.* (2004). Roles of thromboxane A2 and prostacyclin in the development of atherosclerosis in ApoE-deficient mice. *J Clin Invest* 114:784–794; Xiao, C.Y., Hara, A., Yuhki, K., *et al.* (2001). Roles of prostaglandin I2 and thromboxane A2 in cardiac ischemia–reperfusion injury: a study using mice lacking their respective receptors. *Circulation* 104:2210–2215; Cayatte, A.J., Du, Y., Oliver-Krasinski, J. *et al.* (2000). The thromboxane receptor antagonist S18886 but not aspirin inhibits atherogenesis in ApoE-deficient mice: evidence that eicosanoids other than thromboxane contribute to atherosclerosis. *Arterioscler Thromb Vasc Biol* 20:1724–1728; Hirata, T., Kakizuka, A., Ushikubi, F. *et al.*, Arg60 to Leu mutation of the human thromboxane A2 receptor in a dominantly inherited bleeding disorder. *J Clin Invest* 94:1662–1667 (Reporting a naturally occurring TP mutation associated with a mild bleeding disorder).

[49]*See* FDA Drug Safety Communications (January 21, 2014). *FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products* at http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm.

[50]*N Engl J Med 363*(2):109-122 (July 8, 2010).

231. The clinical study reported in the Basaria Paper was prematurely discontinued because the Data and Safety Monitoring Board (DSMB) overseeing the safety of the subjects enrolled in this study observed a significant number of adverse cardiovascular events in the testosterone-treated group.

232. The Basaria Paper concluded, among other things: "In this population of older men with limitations in mobility and a high prevalence of chronic disease, the application of a testosterone gel was associated with an increased risk of cardiovascular adverse events. The small size of the trial and the unique population prevent broader inferences from being made about the safety of testosterone therapy. (ClinicalTrials.gov number, NCT00240981.)."[51]

233. The FDA has noted:

> Testosterone is a hormone essential to the development of male growth and masculine characteristics. Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition.[52] Examples of these conditions include failure of the testicles to produce testosterone because of reasons such as genetic problems or chemotherapy. Other examples include problems with brain structures, called the hypothalamus and pituitary that control the production of testosterone by the testicles.
>
> None of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition. FDA-approved testosterone formulations include the topical gel, transdermal patch, buccal system (applied to upper gum or inner cheek), and injection.[53]

234. These testosterone-containing products are not indicated for the treatment of the *normal* age-related declines in testosterone levels and/or non-specific age-related symptoms.

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[51] *Id.*

[52] The medical conditions are specifically delineated in the product PPI.

[53] FDA Drug Safety Communications (January 21, 2014). *FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products* at http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm.

235. Testosterone-containing product manufacturers marketed and promoted these products for treatment of both the *normal* age-related declines in testosterone levels and/or non-specific age-related symptoms.

236. Constellations of age-related physiologic findings, including the *normal* age-related declines in testosterone levels and non-specific age-related symptoms, have been conscripted into a pharmaceutical industry created pseudo-medical condition known as "Low-T."

237. “Low T” is not a disease, and does not have an International Classification of Disease (ICD) code.

238. The testosterone-containing product manufacturers set forth herein performed aggressive and highly effective marketing and promotional campaigns directed at both the consuming public and healthcare providers, and have driven a dramatic, unwarranted, and dangerous increase in testosterone product usage over the past decade. This has created a substantial public health problem in the United States and elsewhere.

239. A substantial number of prescription sales are for clinical uses of testosterone that are not approved by the FDA,[54] and are the result of aggressive and pervasive “off-label” promotion by testosterone-containing product manufacturers.

240. The scientifically established propensity of testosterone products to cause hypercoagulabilty and hyperviscosity syndromes was known prior to the launch of the testosterone-containing products described herein, and should have been warned about to physicians and the public *ab initio*.[55]

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[54] Between 2001 and 2011, testosterone replacement therapy has increased three-fold. *See* Baillargeon, J., Urban, R.J., and Ottenbacher, K.J. (2013). Trends in Androgen Prescribing in the United States. *JAMA* 173(15):1465-1466.

[55] *See, e.g.,* Schrör K., Morinelli T.A.,Masuda A. (1994). Testosterone treatment enhances thromboxane A2 mimetic induced coronary artery vasoconstriction in guinea pigs. *European Journal of Clinical Investigation* 24 (Suppl.

241. The scientifically established propensity of testosterone products to cause hypercoagulabilty and hyperviscosity syndromes was known prior to the launch of the testosterone-containing products described herein, and information concerning these propensities should have been provided in the safety information which the manufacturers herein undertook, as a duty, to provide to consumers and patients.

242. TRT Sponsors AbbVie, Abbott, and Auxilium Pharmaceuticals, Inc., Besins Healthcare, Clarus Therapeutics, Eli Lilly and Company, LillyEndo Pharmaceuticals, Lipocine, MonoSol Rx, TesoRx, Trimel Pharmaceuticals, Upsher Smith Laboratories, and Viramal have stated to the FDA in their *Advisory Committee Industry Briefing Document Testosterone Replacement Therapy* in advance of the September 17, 2014 Advisory Committee[56] hearing: "TRT Sponsors remain committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions."

243. 101. At all times material hereto, despite being "committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions," these testosterone-containing product manufacturers, sellers, distributors, promoters, and marketers made no labelling changes concerning the risks associated with their testosterone containing product use, include the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

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1):50-52; *see also* Adesuyi A. L. Ajayi, A., Mathur, R. *et al.* (1999). Testosterone Increases Human Platelet Thromboxane A_2 Receptor Density and Aggregation Responses. *Circulation* 91**:** 2742-2747.

[56] Joint Meeting for Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSARM AC).

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulean dolens, phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

244. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

5. Inadequate Warnings and Labeling

245. Defendants' marketing strategy has been to aggressively market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

246. Defendants successfully marketed AndroGel and Testopel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

247. Defendants' advertising program, sought to create the image and belief by consumers that the use of AndroGel and Testopel were a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

248. Defendants promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

249. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using AndroGel and Testopel. Defendants deceived potential AndroGel and Testopel users and their physicians by relaying positive information through the press, including AndroGel and Testopel testimonials from retired professional athletes, and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

250. Defendants concealed material relevant information from potential AndroGel and Testopel users, and their physicians, and minimized user and prescriber concern regarding the safety of AndroGel and Testopel, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

251. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represent that Defendants adequately tested AndroGel and Testopel for all likely side effects. The Defendants also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

252. AndroGel and Testopel's prescribing information and medication guide contained within the package materials do not warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

253. The medication guide contained within the package materials instructs patients to tell their healthcare provider the following before initiating use of AndroGel and Testopel:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have kidney or liver problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

However, the prescribing information and medication guide contained within the package materials fail to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. They also fail to instruct patients or physicians to be aware of the presence of comorbid conditions or pre-existing heart disease, which has been proven to double the risk in men under the age of 65 who use testosterone therapy.

254. The prescribing information and medication guide contained within the package materials do warn that the use of these products may result in increased red blood cell count, but do not instruct physicians or patients that it can increase a red blood cell count to the point that it

more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count does not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor does it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%, including the fact that individuals with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

255. The prescribing information and medication guide contained within the package materials do instruct physicians to re-evaluate their patient's hematocrit 3 to 6 months after starting treatment, but they fail to warn patients and their physicians that the product can cause dangerous increases in hematocrit much more rapidly, and also fail to instruct physicians to monitor their patient's hematocrit more frequently.

256. The prescribing information and medication guide contained within the package materials fail to state that testosterone replacement therapy should not be administered to men who have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant because the increase in serum estradiol caused by the drug can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones. They also fail to instruct physicians to screen all patients for underlying clotting traits before prescribing testosterone replacement therapy.

257. The prescribing information and medication guide contained within the package materials fail to warn that use of the product may result in elevated levels of estradiol. They do

not instruct physicians to monitor estradiol levels, nor do they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There is also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

258. The prescribing information and medication guide contained within the package materials do not warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

259. The prescribing information and medication guide contained within the package materials do not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There is no mention of the fact that there is a doubling of the risk of heart attacks in men over the age of 65 who use testosterone replacement therapy, despite the fact that the data supporting this finding has been available for years. Instead, the label only states that the manufacturer lacks any information regarding the safety or efficacy of testosterone therapy for men over the age of 65. This absence of a warning fails to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

260. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, et al. published as article in the Journal of the American Medical Association

entitled Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels ["Vigen Paper"].

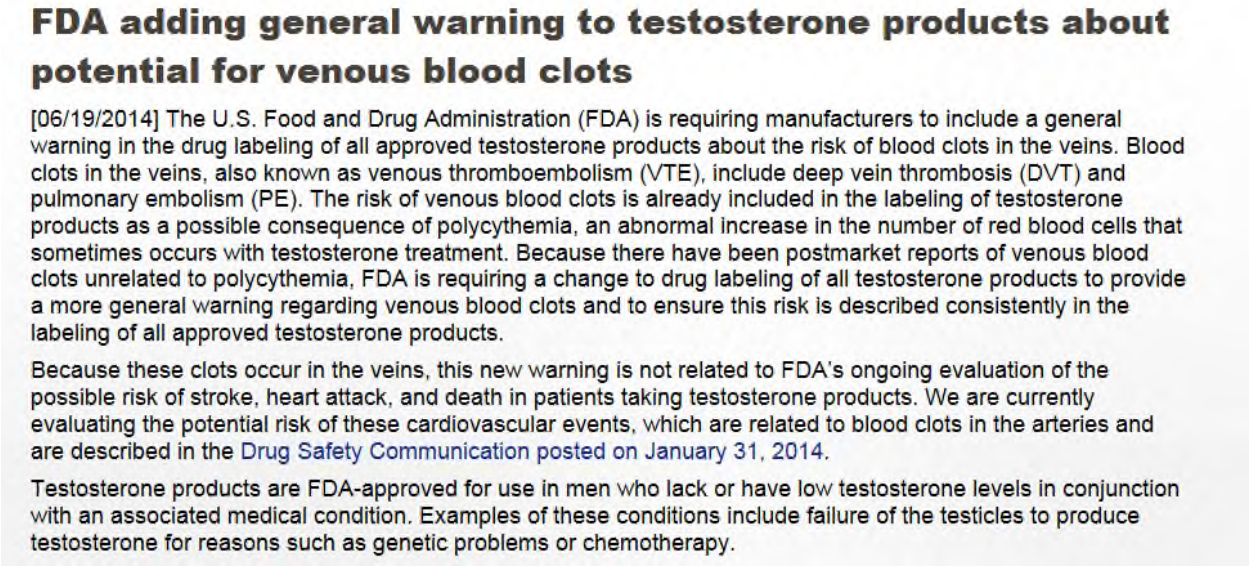
261. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

262. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, et al. published an article in PLOS ONE entitled Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men ["Finkle Paper"].

263. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

264. The increased incidence of heart attack and stroke was foreseeable at the time of the product launch of AndroGel 1% and 1.62%.

265. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the United States Food & Drug Administration (FDA) announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).



FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

266. As a result of this mandate by the FDA, on June 21, 2014, the Defendants updated the prescribing information to provide the general warning required by FDA regarding DVT and PE, and also updated the medication guide for AndroGel and Testopel to include the significant risk of PE as follows: "Blood clots in the legs or lungs. Signs and symptoms of a blood clot in your leg can include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain." However, the prescribing information and the medication guide contained within the package materials still lacks any warning about the risks of elevated estradiol levels, the need to screen for underlying clotting traits, and they contains no warnings for strokes, or for cardiovascular injuries.

267. The marketing and promotion of the product to patients and physicians overstated its benefits by creating the impression that it was a safe and effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

268. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel and Testopel. If Plaintiff and his physician had known the risks and dangers associated with AndroGel and Testopel, the physician would not have prescribed nor would Plaintiff have taken AndroGel and Testopel and consequently would not have been subject to its serious side effects; and/or, Plaintiffs' physicians would have adequately monitored Plaintiffs' hematocrit and estradiol levels, and, as a result, Plaintiffs' injuries would have not otherwise have occurred

6. Case Specific Facts

269. Plaintiff sought specific testing and treatment for "Low T" based upon the representations and medical information provided to him by Defendants through direct-to-consumer educational and information "Low T" awareness campaigns propagated by Abbott, AbbVie, and Auxilium.

270. Had Defendants properly disclosed the risks associated with testosterone, Plaintiff would have avoided the risks of pulmonary embolism by either not using testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

271. Plaintiff's physician would not have prescribed AndroGel and Testopel to his patient had he been advised of and properly warned of the risks of pulmonary embolism caused by or increased with respect to the risk of harm by AndroGel and Testopel.

272. Plaintiff began taking Androgel in approximately October 2012 and continued taking the drug until approximately March 2013. On or about March 22, 2013, Plaintiff had Testopel pellets surgically implanted.

273. On or about March 30, 2013, Plaintiff presented to the hospital and was ultimately diagnosed with a pulmonary embolism.

274. Plaintiff's injuries were directly and proximately caused by or increased in the risk of harm by his use of testosterone by the mechanism of injury as described above in Section I. D. 4.

275. Because of his use of the AndroGel and Testopel, Plaintiff suffered a pulmonary embolism and continues to suffer:

a. physical impairment;

b. loss of life's pleasures;

c. fear and fright;

d. embarrassment and humiliation;

e. economic loss;

f. requirement for medical monitoring relating to his injuries;

g. loss of earnings; and,

h. past, present and future medical expenses.

276. Plaintiff incurred significant medical expenses as a result of the treatment he underwent to treat his injuries, will incur future medical expenses as his injuries are permanent, lost wages as a result of being unable to work, his ability to labor and earn money has been impaired, he is at increased risk for future health problems and disability, and he suffered physical pain and mental anguish.

277. Defendants materially and deceptively misrepresented and mischaracterized the definition of hypogonadism to the Plaintiff and his physician.

278. There was no adequate warning to Plaintiff or his physician that the product presented a risk of developing deep vein thrombosis.

279. Had Plaintiff and his physicians known the true risks associated with the use of testosterone medications, including AndroGel and Testopel, he would not have consumed the AndroGel or Testopel, and/or would have been adequately monitored for its side effects, and as a result, would not have incurred the injuries or damages he did as a result of his use of AndroGel and Testopel.

II. CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

280. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

281. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

282. The AndroGel and Testopel manufactured and/or supplied by Defendants were defective due to inadequate warnings or instructions because Defendants knew or should have known that the products created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

283. Defendants failed to adequately warn consumers and/or their health care providers that AndroGel and Testopel could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

284. Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking AndroGel and Testopel it was necessary to frequently monitor

hematocrit and estradiol levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

285. The AndroGel and Testopel manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of AndroGel and Testopel, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

286. As a direct and proximate result of Plaintiff's reasonably anticipated use of AndroGel and Testopel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

287. Plaintiff, Allyson Schabel, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incident to his use of AndroGel and Testopel. Her damages include, but are not limited to, a loss of society, companionship, services, support, and care. Her losses are permanent and continuing in nature.

Count Two – Negligence

288. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

289. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute,

market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of AndroGel and Testopel.

290. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of AndroGel and Testopel to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular accident, deep vein thrombosis and it sequelae, pulmonary embolism, and sudden cardiovascular death.

291. Defendants had a duty of care when it undertook to provide comprehensive medical information to consumers and patients concerning "Low T" as a medical diagnostic entity; and, to educate and inform consumers and patients about "Low T;" and, to provide consumers and patients with the means for self-diagnostic screening and in-home testing for "Low T."

292. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of AndroGel and Testopel to heart attack, stroke, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

293. Defendant's duty of care owed to consumers and patients included providing accurate, true, and correct information concerning:

-hypogonadism and its diagnostic criteria;

-the FDA-approved indications for the clinical use of the AndroGel and Testopel products;

-the clinical safety and effectiveness profiles of AndroGel and Testopel; and,

-appropriate, complete, and accurate warnings concerning the adverse effects of AndroGel and Testopel, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

294. At all times herein mentioned, Defendants breached their duty of care by negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold AndroGel and Testopel and failed to adequately test and warn of the risks and dangers of AndroGel and Testopel as described herein.

295. The Defendants negligently and carelessly disregarded the applicable regulations and industry standards regarding the prohibition against off-label marketing, misbranding and label expansion, and as a result millions of men, including the Plaintiff, were prescribed AndroGel and Testopel unnecessarily, and therefore needlessly exposed to serious health risks for which there were no or inadequate warnings.

296. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for AndroGel and Testopel, including Plaintiff's prescribing physician. Specifically, the FDA had not approved AndroGel and Testopel or any other testosterone-containing preparation for the treatment of "Low T."

297. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted the testosterone-containing product AndroGel and Testopel with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

298. Despite the fact that Defendants knew or should have known that AndroGel and Testopel caused unreasonable, dangerous side effects, Defendants continued to market AndroGel and Testopel to consumers including Plaintiff, when there were safer alternative methods and/or

no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that AndroGel and Testopel marketing materials claim are caused by "Low T".

299. At all times material hereto, Defendants misbranded the AndroGel and Testopel product on an on-going and continuous basis, and failed to warn physicians and patients that AndroGel and Testopel was not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

300. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with AndroGel and Testopel use.

301. As marketed, detailed, and promoted to physicians, including Plaintiff's prescribing physician, Defendants failed to warn that AndroGel and Testopel caused, or increased the risk of harm of, cardiovascular and cerebrovascular injuries, including myocardial infarction and cerebrovascular accident, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

302. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

303. Defendants' negligence was a proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

304. Plaintiff, Allyson Schabel, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incident to his use of Androgel and Testopel. Her

damages include, but are not limited to, a loss of society, companionship, services, support, and care. Her losses are permanent and continuing in nature.

Count Three – Breach of Implied Warranty

305. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

306. Prior to the time that the aforementioned products were used by the Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that AndroGel and Testopel were of merchantable quality and safe and fit for the use for which it was intended.

307. Specifically, the Defendants warranted to Plaintiff that its product was intended to treat a condition called "LowT" and that it was safe and fit for that use, but the Defendants failed to disclose that "LowT" is not a recognized medical condition and that its testosterone product was not FDA approved to treat any such condition.

308. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including AndroGel and Testopel, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using AndroGel and Testopel. As a result, the Plaintiff used Defendants' product as it was warranted to be intended.

309. AndroGel and Testopel was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that AndroGel and Testopel have dangerous propensities when used as intended and will cause severe injuries to users.

310. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

311. Plaintiff, Allyson Schabel, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incident to his use of AndroGel and Testopel. Her damages include, but are not limited to, a loss of society, companionship, services, support, and care. Her losses are permanent and continuing in nature.

Count Four - Fraud

312. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

313. Through a sophisticated and well-orchestrated marketing campaign, the Defendants set out to invent a fictitious disease/medical condition that it called "LowT", and then purposely deceived the Plaintiff and his physicians into believing that this was a real disease/medical condition and that Plaintiff suffered from it. Defendants did this through marketing a set of generic and common conditions in middle-aged men, and representing that these conditions were "symptoms" of "LowT". Those commonly occurring conditions were listed in the "Is It LowT Quiz", and included:

- Being tired after dinner
- Diminished ability to play sports
- Lack of energy
- Being sad
- Being grumpy
- Decreased libido

Each of these purported "symptoms" of "LowT" are normal and common conditions for men over the age of 40, and especially common in men over the age of 50.

314. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroGel and Testopel, and up to the present, knew that their products could cause an increase in hematocrit in patients to a level that more than doubles their risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of their products could result in a dramatic increase in serum estradiol levels, yet the Defendants willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning AndroGel and Testopel, which the Defendants had a duty to disclose.

315. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and Testopel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using AndroGel and Testopel. Defendants knew of the foregoing, that AndroGel and Testopel are not safe, fit and effective for human consumption, that using AndroGel and Testopel are hazardous to health, and that AndroGel and Testopel have a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

316. Defendants knowingly, falsely, deceptively, and inaccurately designated the physiologic decrease in men's testosterone levels and the age-related symptoms men experience with aging as a form of acquired hypogonadism with the intent to deceive physicians into prescribing Androgel and Testopel for "off-label" indications for clinical use; and, to engage in "label expansion" of the AndroGel and Testopel products; and, to drive increasing consumer and patient demand for AndroGel and Testopel prescriptions.

317. Defendants knowingly, falsely, deceptively, and inaccurately misstated the clinical effectiveness profile of AndroGel and Testopel to physicians, to include statements concerning the effectiveness of treatment of the age-related signs and symptoms included on the "Interactive ADAM Questionnaire." There was no double-blind, placebo-controlled, randomized, sufficiently powered, and independent study or clinical investigation or clinical evidence to support this use of AndroGel and Testopel, and no approval by the FDA to warrant promotion of these indications for clinical use.

318. Defendants knowingly, falsely, deceptively, and inaccurately designated and represented that the physiologic decline in men's testosterone levels and the age-related symptoms men experience with advancing age, as a form of "acquired hypogonadism" with the intent to confuse and deceive consumers and patients, and to foster the belief by consumers and patients, including Plaintiff, that they harbored a "disease" or pathologic medical condition that was appropriately treated with the AndroGel and Testopel products.

319. Defendants concealed and suppressed the true facts concerning AndroGel and Testopel, and the actual disease for which it has been FDA approved to treat (Hypogonadism), with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe AndroGel and Testopel, and Plaintiff would not have used AndroGel and Testopel, if they were aware of the true facts concerning its dangers.

320. Defendants undertook to inform and educate consumers about the diagnostic hallmarks of "Low T," and engaged in and encouraged mass consumer screening for "Low T" via patient-directed questionnaires, quizzes, and information, as part of a mass marketing effort to encourage patients to seek treatment for "Low T," while having actual knowledge that AndroGel and Testopel were not indicated for the treatment of "Low T," nor was it proven to be

clinically safe and effective for treating "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

321. Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that it provided to consumers and patients through its multi-platform marketing, promotional, educational, and awareness campaigns concerning the AndroGel and Testopel products and its indications for clinical use; and further knew that consumers and patients would make treatment choices and exercise treatment options about their use of the AndroGel and Testopel product in reliance upon this information.

322. Defendants deceived physicians by explicitly or implicitly claiming that the treatment of "Low T" was an FDA-approved clinical indication for use of AndroGel and Testopel, when in fact it was an "off-label" indication for clinical use.

323. Consumers, including Plaintiff, required, and should have been provided with, truthful, accurate, and correct information concerning the FDA-approved indications for the clinical use for AndroGel and Testopel and the clinical safety and effectiveness profiles for AndroGel and Testopel, including information concerning the "off-label" use of the AndroGel and Testopel products.

324. Plaintiff relied on the fraudulent and deceptive representations made by the Defendant to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that AndroGel and Testopel were FDA approved to treat a condition called "LowT", and that the Defendant's testosterone drug was a safe and effective treatment for his "LowT".

325. Plaintiff would not have sought or continued treatment for "Low T" or administered AndroGel or Testopel had he been provided with adequate, true, accurate, and

correct information by Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of AndroGel and Testopel, and the fact that "Low T" was not an FDA-approved indication for clinical use of AndroGel and Testopel.

326. Plaintiff would not have sought or continued treatment for "Low T," or administered AndroGel or Testopel, had he been provided with adequate, true, accurate, and correct information by Defendants, including information that there were no proven clinical profiles of safety or effectiveness for the use of AndroGel and Testopel to treat "Low T."

327. During the detailing, marketing, and promotion to physicians, neither Defendants nor the co-promoters who were detailing AndroGel and Testopel on behalf of Defendants warned physicians, including Plaintiff's prescribing physician, that AndroGel and Testopel caused or increased the risk of harm of cerebrovascular accident and neurologic injuries.

328. Defendants, through its national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs, undertook to inform the consuming public and patients, including Plaintiff, about a "disease" Defendants denominated and characterized as "Low T."

329. These materials did reach Plaintiff, and he relied upon these materials in reaching his decision to purchase, use, and continue the use of AndroGel and Testopel throughout his course of testosterone therapy.

330. Plaintiff would not have taken AndroGel or Testopel had the educational and informational materials made available to him by Defendants, and upon which he relied to his detriment, informed him about the risks of cardiovascular events and cerebrovascular accident with product use.

331. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

Count Five – Negligent Misrepresentation

332. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

333. From the time AndroGel and Testopel were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that "LowT" was an actual disease/medical condition for which medical treatment was indicated, and that AndroGel and Testopel were safe, fit, effective, and FDA approved for human consumption to treat "LowT". At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and Testopel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

334. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

335. The representations by the Defendants were in fact false, in that AndroGel and Testopel are not safe, fit and effective for human consumption, using AndroGel and Testopel are

hazardous to health, and AndroGel and Testopel have a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

336. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of AndroGel and Testopel.

337. Plaintiff relied on the misrepresentations made by the Defendant to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that AndroGel and Testopel were FDA approved to treat a condition called "LowT", and that the Defendant's testosterone drug was a safe and effective treatment for his "LowT".

338. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use AndroGel and Testopel. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used AndroGel and Testopel. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

339. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

340. Plaintiff, Allyson Schabel, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incident to his use of AndroGel and Testopel. Her damages include, but are not limited to, a loss of society, companionship, services, support, and care. Her losses are permanent and continuing in nature.

Count Six - Design Defect

377. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

378. AndroGel and Testopel are defective in their design or formulation in that they are not reasonably fit, suitable, or safe for their intended purpose and/or that the foreseeable risks exceed the benefits associated with their design and formulation.

379. At all times material to this action, Androgel and Testopel were expected to reach, and did reach, consumers in the State of Illinois and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

380. At all times material to this action, Androgel and Testopel were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, AndroGel and Testopel contained unreasonably dangerous design defects and were not reasonably safe for their intended use, subjecting Plaintiff to risks that exceeded the benefits of the subject products including, but not limited to, permanent personal injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarctions, and other serious injuries and side effects;

b. When placed in the stream of commerce, AndroGel and Testopel were defective in design and formulation, making their use more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated

with the other medications and similar drugs on the market to treat low testosterone;

c. The design defects found in AndroGel and Testopel existed before they left the control of the Defendants;

d. AndroGel and Testopel were insufficiently and inadequately tested;

e. AndroGel and Testopel caused harmful side effects in Plaintiff and the public as a whole that outweighed any potential utility; and

f. AndroGel and Testopel were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff of the full nature and extent of the risks and side effects associated with their use, thereby rendering Defendants liable to Plaintiff.

381. In addition, at the time Androgel and Testopel left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the products. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products' utility.

382. Plaintiff, Allyson Schabel, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incident to his use of AndroGel and Testopel. Her damages include, but are not limited to, a loss of society, companionship, services, support, and care. Her losses are permanent and continuing in nature.

Count Seven-Negligence Per Se—Violation of 21 U.S.C. §§ 331(a) & 352

383. As part of their duty to exercise reasonable care, Defendants were obligated to follow public laws and regulations enacted to protect the safety of persons such as Plaintiff, including 21 U.S.C. § 331(a), § 352, and other statutes and regulations which make it unlawful to sell misbranded prescription drug products.

384. The labeling for AndroGel and Testopel failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (j), and the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits the sale of misbranded drugs.

385. The label and package insert for AndroGel and Testopel are misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe testosterone.

386. AndroGel and Testopel are misbranded pursuant to 21 U.S.C. § 352 because:

a. Words, statements, or other information required under that section are not prominently placed with such conspicuousness and in such ways as to render it likely to be read and understood by the ordinary individual or prescriber under customary conditions of purchase and use.

b. The labeling does not bear adequate directions for use, and the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage, methods, or application in such manner and form as are necessary for the protection of patients.

c. It is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

387. Because Defendants had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to misbrand testosterone, and because they violated this duty, they are guilty of negligence per se.

388. Androgel and Testopel are misbranded pursuant to 21 C.F.R. § 201.56 because the labeling were not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

389. Defendants violated 21 C.F.R. § 201.57 because:

a. As shown, the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., heart attacks, strokes, and other blood clotting injuries).

b. They failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug AndroGel and Testopel.

c. The safety considerations regarding testosterone are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

d. The labeling fails to describe serious adverse reactions and potential safety hazards, and steps that should be taken if they occur.

e. The labeling does not state an upper limit dosing beyond which safety and effectiveness have not been established.

390. AndroGel and Testopel violate 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

391. AndroGel and Testopel violate 21 C.F.R. § 310.303 in that they are not safe and effective for their intended use.

392. Defendants violated 21 C.F.R. § 310.305 and § 314.80 by:

a. Failing to report adverse events associated with testosterone as soon as possible or at least within 15 days of the initial receipt by Defendants of the adverse drug experience.

b. Failing to conduct an investigation of each adverse event associated with testosterone, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

c. Failing to provide periodic reports to the FDA containing (1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (2) an Adverse Reaction Report for each adverse drug experience not

> already reported under the Post marketing 15-day Alert report, (3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) and/or (4) a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

393. Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of testosterone or otherwise received by Defendants from any sources, including information from any clinical or epidemiological studies, animal studies, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities.

394. Defendants failed to meet the standard of care set out in these statutes and regulations, which were intended for the benefit of individual consumers such as Plaintiff, making Defendants liable to Plaintiff. Because each of them violated the duties imposed by these statutes and regulations, they are guilty of negligence per se.

395. As a direct and proximate result of the actions and inactions of Defendants, Plaintiff suffered damages, including personal injuries, economic damages, and non-economic damages. Defendants' conduct was further wanton, egregious, and reckless so as to warrant the award of punitive damages.

396. Plaintiff, Allyson Schabel, sustained a loss of consortium as a result of the injuries and damages sustained by her husband incident to his use of AndroGel and Testopel. Her

damages include, but are not limited to, a loss of society, companionship, services, support, and care. Her losses are permanent and continuing in nature.

Punitive Damages Allegations

397. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

398. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other AndroGel and Testopel users and for the primary purpose of increasing Defendants' profits from the sale and distribution of AndroGel and Testopel. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

399. Prior to the manufacturing, sale, and distribution of AndroGel and Testopel, Defendants knew that said medications were in a defective condition as previously described herein and knew that those who were prescribed the medications would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medications presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroGel and Testopel.

400. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in AndroGel and Testopel and failed to warn the public,

including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in AndroGel and Testopel. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of AndroGel and Testopel knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

401. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against the Defendant, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

Dated: February 17, 2015

Respectfully submitted,

/s/Brandon L. Bogle_____
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